UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

PFIZER INC.,

Defendant.

Civil Action No. 03 10167 RGS

TEVA'S SUPPLEMENTAL BRIEF
IN OPPOSITION TO PFIZER'S MOTION TO DISMISS
FOR LACK OF SUBJECT MATTER JURISDICTION

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INTRODUCTION

Teva submits this Supplemental Brief in opposition to Pfizer's motion to dismiss this case for lack of subject matter jurisdiction. This Supplemental Brief is being filed pursuant to the Court's order that the parties submit supplemental papers discussing both *Dr. Reddy's Labs. v. Pfizer*, 2003 WL 21638254 (D.N.J. July 8, 2003) (copy attached as Supplemental Exhibit 1), and Teva's provision of product samples to Pfizer. Although the district court in *Dr. Reddy's* dismissed the complaint at issue, that decision does not control here, since Teva's action is factually distinct from the *Dr. Reddy's* situation and since the *Dr. Reddy's* decision does not give appropriate weight to the factors which warrant jurisdiction. Thus, this Court should exercise its discretion to accept jurisdiction over Teva's complaint.

Dr. Reddy's involved a claim for a declaratory judgment that the filing of an ANDA for sertraline does not infringe Pfizer's '699 patent. Pfizer argued that declaratory judgment jurisdiction was lacking because (1) the plaintiff Dr. Reddy's Laboratories ("DRL") had not performed an act that could constitute infringement or taken steps with the intent to conduct such activity, and (2) Pfizer's actions had not created a reasonable apprehension that DRL will be sued.

On the first issue, the *Dr. Reddy's* court correctly held that the filing of the ANDA satisfies the immediacy prong of the jurisdictional test, because it demonstrates a real case or controversy as to infringement of the '699 patent. The court readily reached this conclusion because such an ANDA filing is specifically defined in the patent statute as an act of infringement. For the same reason, Teva's declaratory judgment action also satisfies this prong of the test.

On the second issue, the *Dr. Reddy's* decision concluded that DRL did not reasonably apprehend suit. Teva's suit is factually different from the facts in *Dr. Reddy's*. The rationale for the *Dr. Reddy's* decision is that Pfizer should be provided an opportunity to investigate infringement. Here, Teva offered to provide product samples to Pfizer, and in fact did provide such samples so that there would be no doubt about its ability to investigate. In July 2003, Pfizer returned Teva's samples without even so much as opening them, thus demonstrating that Pfizer either has completed its investigation or has no intention of undertaking an investigation. Thus, even if "opportunity to investigate" were the standard, it has been satisfied here. Pfizer's actions here demonstrate that it wishes to duck Teva and leave a suit hanging over its head. Pfizer knows that testing would force its hand—either it would be required to tell Teva that it does not infringe its patent and provide it with a covenant not to sue, or to come clean with its intention to sue Teva for infringement. Its refusal to test or provide a covenant to Teva speaks volumes, and confirms Teva's reasonable apprehension. In addition to the factual differences from *Dr. Reddy's*, and as explained below, the *Dr. Reddy's* decision also did not give proper weight to other facts showing the reasonableness of DRL's apprehension of suit.

Finally, it is important to recognize that the *Dr. Reddy's* court did not hold that jurisdiction was lacking as a matter of law. Rather, the court merely declined to exercise its *discretion* at this time to hear the declaratory judgment action. The overriding Congressional purpose behind the Hatch-Waxman Act is to benefit the public, and that goal is accomplished by allowing generic companies to enter the market at the earliest possible date. Teva submits that, when viewed in this light, this Court should exercise its discretion to permit this case to go forward so that this controversy may be adjudicated on its merits.

ARGUMENT

I. The *Dr. Reddy's* Court Correctly Held That There Was an Immediate Controversy

In its briefs, Pfizer's primary argument in support of its motion to dismiss was that there is no immediate controversy between the parties because Teva does not have the immediate ability to market its sertraline product. The same exact argument was flatly rejected by the *Dr. Reddy's* court.

The *Dr. Reddy's* court held that DRL's submission of its ANDA satisfies the immediacy prong of the test for declaratory judgment jurisdiction. *See Dr. Reddy's*, 2003 WL 21638254 at *5. Expressing reasoning similar to that set out in Teva's principal brief in this case, the *Dr. Reddy's* court concluded that DRL's ANDA filing is a "present activity which could constitute infringement." *Id.* at *3 (quoting *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999)). In particular, the court noted that 35 U.S.C. § 271(e)(2)(A) unambiguously defines an ANDA submission as "an act of infringement" when its purpose is to manufacture and sell a drug claimed in an unexpired patent. *Id.*

The *Dr. Reddy's* court stated that, because an ANDA filing constitutes a sufficient case or controversy to support an infringement suit brought by the patent owner, there is "no principled reason" why the same ANDA filing should not constitute a sufficient case or controversy to support a declaratory judgment action to establish non-infringement. *Id.* at *4. The *Dr. Reddy's* court dismissed the cases relied upon by Pfizer because Pfizer's cases did not involve an ANDA. *Id.* For the same reasons as expressed in *Dr. Reddy's*, the present case also satisfies the immediacy prong of the Federal Circuit's test for declaratory judgment jurisdiction.

II. The *Dr. Reddy's* Court's Decision Not To Exercise Declaratory Judgment Jurisdiction Is Factually Inapplicable To This Case and Legally Flawed

A. Pfizer's Refusal to Test Teva's Samples or Provide a Covenant Not to Sue Is Strong Evidence of the Reasonableness of Teva's Apprehension of Suit

The *Dr. Reddy's* court was concerned that Pfizer had not been provided an opportunity to investigate the DRL products to determine if they infringed Pfizer's '699 patent. *Id.* at *7-8. This case presents different facts, however, because Teva offered to provide Pfizer with samples in December 2002 and did provide samples to Pfizer in July 2003. Pfizer's return of those samples is a litigation tactic to avoid (i) jurisdiction in this Court and (ii) providing Teva a covenant not to sue. Pfizer's tactics, which were not present in the *Dr. Reddy's* decision, are strong evidence of Teva's reasonable apprehension of suit.

At one point in time, Pfizer did seem interested in investigating Teva's product. In December 2002, Pfizer sent Teva a letter requesting product samples for the purpose of evaluating whether Teva's ANDA product infringes Pfizer's patent. [Sup. Ex. 2.] Teva agreed to Pfizer's request, and stated that it was willing to provide product samples, subject to a confidentiality agreement. [Sup. Ex. 3.] Pfizer then declined to enter into the agreement, and Teva filed the present lawsuit.

Teva also asked that Pfizer provide Teva with a covenant not to sue. [Teva Br. at 6.] In addition, Teva later sent Pfizer samples of Teva's proposed product, to enable Pfizer to determine conclusively that Teva's product would not infringe Pfizer's '699 patent. [Sup. Ex. 4.] Teva again advised Pfizer that once it confirmed that Teva's proposed product did not infringe Pfizer's '699 patent and granted a covenant not to sue, Teva would be willing to enter into a joint motion seeking termination of the present action. [Sup. Ex. 5.] Shortly after receiving Teva's

samples, Pfizer returned them unopened. [Sup. Ex. 6.] Teva asked Pfizer to reconsider, which it has refused to do. [Sup. Ex. 7.]

Thus, the concern of the *Dr. Reddy's* court that Pfizer have an opportunity to test the generic product is not applicable here. Had Pfizer been interested in investigating infringement, it would have accepted Teva's samples and conducted tests with those samples. Moreover, Pfizer's failure to provide Teva with a covenant not to sue is strong evidence that Pfizer does intend to sue Teva.

Teva also notes that "opportunity to investigate" is not a standard set forth in any precedent. Indeed, the Hatch-Waxman Act explicitly provides a patent owner with the basis for a generic company's patent challenge by requiring that ANDA filers serve a "detailed statement" of the reasons for the patent challenge. *See* 21 U.S.C. § 355(b)(3)(B). In addition, the Hatch-Waxman Act allows the patent owner time to review this detailed statement by prohibiting declaratory judgment actions for forty-five days after the ANDA filing. *See id.* at § 355(j)(5)(B)(2). Teva filed the required "detailed statement" in this case, and then went above and beyond the Hatch-Waxman Act requirements by providing product samples to Pfizer. Simply put, "opportunity to investigate" is a red herring here.

B. The *Dr. Reddy's* Court Did Not Appropriately Weigh the Factors Relevant To Apprehension of Suit

Even on the facts before it, the *Dr. Reddy's* court misapplied the relevant standards. For example, the *Dr. Reddy's* decision erroneously concluded that the submission of an NDA with an Orange Book listing does not by itself create a reasonable apprehension that an ANDA filer will be sued by the owner of the listed patent. *Id.* at *5. The court rejected Judge Gajarsa's concurring opinion in *Minnesota Mining & Mfg. v. Barr Labs.*, 289 F.3d 775 (Fed. Cir. 2002),

which stated that such a filing *does* create a reasonable apprehension of suit. *Dr. Reddy's*, 2003 WL 21638254 at *5 (emphasis in original). Judge Gajarsa correctly relied on the Hatch-Waxman Act, which provides that the listing of a patent in the Orange Book "requires the patentee to maintain that an infringement suit could 'reasonably be asserted' against one who 'engages in the manufacture, use or sale of the drug.'" *Minnesota Mining*, 289 F.3d at 791 (quoting 21 U.S.C. § 355(b)(1)). Since Pfizer has filed papers with the FDA certifying that its '699 patent could "reasonably be asserted" against an ANDA filer such as Teva, this alone is enough to create in Teva a "reasonable apprehension" that it will be sued.

The *Dr. Reddy's* court also erroneously considered the fact that Pfizer had not sued DRL within forty-five days of DRL's ANDA filing as "objective evidence" that Pfizer did not intend to sue DRL. *See Dr. Reddy's*, 2003 WL 21638254 at *5. The whole point of the Declaratory Judgment Act is to allow a potential defendant to precipitate a suit that has not yet been brought. The Act would be completely undermined if courts must decline jurisdiction because the declaratory judgment plaintiff had not been sued at the earliest possible date. In response to DRL's argument that Pfizer did not benefit by bringing suit within forty-five days of DRL's ANDA, the court noted that Pfizer had sued Ivax within forty-five days of Ivax's ANDA. *Id.* at n.7. However, the fact that Pfizer sued Ivax within the forty-five day period, but did not sue DRL or Teva within the forty-five day period, does not show that Pfizer has no interest in ever suing DRL or Teva. Indeed, Pfizer's decision not to sue DRL or Teva is readily explained by the fact that Pfizer can seek to forestall generic competition from *these firms* by preserving Ivax's 180-day generic exclusivity, while leaving a cloud of litigation hanging over them as their products near FDA approval.

The *Dr. Reddy's* court also gave insufficient weight to Pfizer's suit against Ivax, which involved the same NDA and same '699 patent, as well as to Pfizer's history of aggressive assertion of its other patents. *Id.* at *6-7. The court's analysis was contrary to precedent and common commercial experience, which teaches that a company that aggressively enforces its patents in general is likely to aggressively enforce a particular patent at issue. In recognition of this fact, the courts have held that such suits evidence "not only an intent but a willingness and capacity [on the part of the patentee] to employ litigation in pursuit of its patent rights." *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 737 (Fed. Cir. 1988). The *Dr. Reddy's* court noted that Pfizer had not "publicly commented or acted with regards to DRL's ANDA submission, other than a refusal to concede its legal rights with regards to the '699 patent." *Dr. Reddy's*, 2003 WL 21638254 at *5. However, the conduct that creates a reasonable apprehension of suit need not be a specific charge of infringement directed at a particular potential defendant. *See Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987).

Finally, the court should not have dismissed DRL's current apprehension of an impending suit simply because DRL was not sued immediately. *See Dr. Reddy's*, 2003 WL 21638254 at *6 & *7 n.12. The issue under the Federal Circuit's *Amana Refrigeration* test is whether the patent owner has taken an action which creates a "reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit." *Amana Refrigeration,* 172 F.3d at 855. Indeed, this aspect of the *Dr. Reddy's* decision is difficult to reconcile with the court's ruling a few pages earlier that DRL met the immediacy prong of *Amana Refrigeration's* jurisdictional test. *See Dr. Reddy's*, 2003 WL 21638254 at *3-5.

As noted in Teva's principal brief, Pfizer's revenue from sertraline is more than $2 billion per year. Although Pfizer may think it has a good tactical reason for not suing Teva *now*, because ducking the Teva controversy leaves litigation hanging over Teva and could result in later competition from it, Pfizer has strong reasons for eventually bringing such a suit as Teva's ANDA is approved. Suing Teva could further delay competition from Teva. Historically, generic firms challenging patents under the "Paragraph IV" procedures of the Hatch-Waxman Act have been loathe to market products prior to court decisions adjudicating their rights, no matter how small the risk of loss, since the exorbitant profits made by companies like Pfizer can lead to the specter of large damage claims (based on the alleged loss of monopoly profits). A generic pharmaceutical developer should not have to wait years to achieve resolution of an immediate controversy, while the patent owner willfully buries its head in the sand. As discussed in more detail in Teva's principal brief, the Hatch-Waxman Act was designed to allow ANDA filers to adjudicate these issues promptly upon filing an ANDA. [Teva Br. at 13-14.]

When this Court assigns the proper weight to these facts, the balance strongly favors retaining this action and denying Pfizer's motion to dismiss. Had *Dr. Reddy's* made the appropriate weighing of the circumstances, it should not have dismissed that case. Moreover, Teva's case differs fundamentally because of Pfizer's refusal to test Teva's product.

III. The Need for a Court Decision Triggering the Exclusivity Period Is Enough to Create Declaratory Judgment Jurisdiction

In his *Minnesota Mining* concurrence, Judge Gajarsa stated that the inability of a second ANDA filer such as Teva to market a product without a court decision, where there has been a delay in the start of the first ANDA filer's 180-exclusivity period, may create a sufficient case or controversy for purposes of a declaratory judgment action. *See Minnesota Mining*, 289 F.3d at

791 (citing *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998)). Although the *Dr. Reddy's* court did not disagree with Judge Gajarsa, it stated that, "[r]egardless of whether a statutory bottleneck is sufficient to create case or controversy jurisdiction," this argument was unpersuasive as a basis for the court to exercise jurisdiction. *Dr. Reddy's*, at *7.

The *Dr. Reddy's* court apparently believed that triggering the 180-day exclusivity period before Ivax begins to actually market its product in June 2006 (assuming Ivax did go to market then) would negate "the benefits conferred upon the first generic entrant as an incentive to encourage generic producers of drugs." *Id.* According to the court, such a triggering would "nullify the statutory benefit given as an incentive for generic companies who take the greatest risk of being the first generic entrant on the market." *Id.* However, courts have held that Congress provided the 180-exclusity period to run from the date of *any* successful court challenge, thus encouraging prompt generic competition. *See Minnesota Mining*, 289 F.3d at 780. Indeed, it would be contrary to the very purpose of the Hatch-Waxman Act to delay entry by a second ANDA filer simply because a first filer had not achieved a court decision in its case. *Id.* "Congress wanted second ANDA filers to be able to manufacture their drugs quickly if they could prove noninfringement." *Id.* at 789 (Gajarsa, J., concurring). The purpose behind the 180-day exclusivity period—to encourage early generic challenges and the resulting competition—was frustrated when Pfizer settled *Pfizer v. Ivax* and then attempted to evade resolution of the Teva and DRL challenges.

The *Dr. Reddy's* court failed to appreciate that the Pfizer/Ivax settlement frustrates the statutory intent and denies the public the benefit of having earlier competition in the marketplace. The bottleneck can be removed by this Court exercising its discretion to allow the present case to go forward.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Teva's principal brief, this Court should deny Pfizer's motion to dismiss this case for lack of subject matter jurisdiction.

Respectfully submitted,

Dated: 10/15/03

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I hereby certify that a true copy of the above document was served upon the attorneys of record for each party by ~~hand~~/mail.

Date: 10/15/03